

20. The pharmaceutical tablet of claim 19 further comprising a disintegrant selected from the group consisting of croscarmellose sodium, sodium starch glycolate and crospovidone.

REMARKS

Claims 1 and 5-14 now stand rejected under 35 USC 102(b) as allegedly being anticipated by Crisp et al (US 4,820,833).

Claims 1-14 now stand rejected under 35 USC 103(a)) as allegedly being obvious over Crisp et al (US 4,820,833). Applicant therefore has amended the claims to more particularly define over the alleged prior art of record.

Full support for newly provided claims 15 through 20 are found in the disclosure. No new matter has been added.

Before commencing any arguments in relation to the Examiner's rejection under 35 U.S.C. 102 or 103, Applicant would respectfully like to review some of the excerpted jurisprudence from which he will draw inferences and conclusions when formulating specific remarks relating to the prior art of record within the instant application.

ANTICIPATION

The following excerpts of U.S. case law represent Applicant's understanding of the test for novelty.

In Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986) ("It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention, and that such a determination is one of fact.").

In re Donohue, 766 F.2d 531, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985) ("an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device.").

It is well settled that prior art under 35 USC Section 102(b) must sufficiently describe the claimed invention to have placed the public in possession of it Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention Accordingly, even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it is not enabling It is not, however, necessary that an invention disclosed in the publication shall have actually been made in order to satisfy the enabling requirement.

In Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1574, 224 U.S.P.Q. 209, 411 (Fed. Cir. 1984) ("exclusion of a claimed element from a prior art reference is enough to negate anticipation by that reference").

In Tights, Inc. v. Acme-McCravy Corp., 541, F.2d 1047, 191 U.S.P.Q. 305 (4th Cir. 1976); Saf-Gard Prods., Inc. v. Service Parts, Inc., 532 F.2d 1266, 190 U.S.P.Q. 455 (9th Cir. 1976); Shanklin Corp. v. Springfield Photo Mount Co., 521 F.2d 609, 187 U.S.P.Q. 129 (1st Cir. 1975) ("To anticipate under section 102, a prior art reference must disclose all the elements of the claimed invention or their equivalents functioning in essentially the same way.").

In Re Hart v. Baarcke, 186 U.S.P.Q. 275-278 (S.D. FAL. 1975) one foreign publication no matter how obscure may be sufficient to invalidate a patent claim if it clearly and definitely discloses the elements of the patents in suit.

In W. Robinson, The Law of Patents for Useful Inventions section 325-327 (1890) the publication must be 1) a work of public character, intended for general use 2) within the reach of the public. A work of public character is such a book or other printed document as is intended and employed for the communication of ideas to persons in general as distinguished from particular individuals Private communications although printed do not come under this description, whether designed for the use of single persons or of a few restricted groups of persons But though the subject of the publication may be highly technical, and therefore interesting only to a single class of individuals, it is prepared for general circulation in that class, it is a public not a private work

It must have been actually published in such a manner that anyone who chooses may avail himself of the information it contains It is not necessary that many copies of the work should have been printed, nor that its distribution should have been extensive, for the deposit of a single copy in a library to which the public have or can obtain admission places the work within the reach of all. Nor is it requisite that any person should have read or seen it, since the accessibility of knowledge, and not its actual possession, is all that any inventor can secure. And even though the information be so intermingled with discussions relative to other subjects that it may easily escape attention, and would require some skill and patience to extract it, the publication will still be sufficient.

In re Beno (1985) 768 F.2d 1340, 226 U.S.P.Q. 683 (Fed. Cir. 1985) a prior art patent or published application is a reference only for that which it teaches.

The scope of a patent's claims determines what infringes the patent; it is no measure of what it discloses. A patent discloses only that which it describes, whether specifically or in general terms, so as to convey intelligence to one capable of understanding.

Aluminum Co. of America v. Spiry Products Inc., 285 F. 2d 911, 922, 127 U.S.P.Q. 394 (6th Cir. 1960); Borg-Warner Corporation v. Mall Tool Co. 220 F. 2d 803, 805, 105 U.S.P.Q. 147 (7th Cir. 1955) a foreign patent is to be measured as anticipatory, not by what might have been made out of it, but what is clearly and definitely expressed in it. An American patent is not anticipated by a prior foreign patent, unless the latter exhibits the invention in such full, clear, and exact terms as to enable any person skilled in the art to practice it without the necessity of making experiments.

In re Mortin (1961) 288 F.2d 708, 711, 129 U.S.P.Q. 227 (C.C.P.A. 1961) the state of the art does not depend on the provincial view that the available knowledge is only that published in one locality or contained only in domestic patents. Appellant . . . attempts to disparage the value of the French patent as a reference on the ground that it is a foreign patent and is good for only what it clearly and definitely discloses. That statement is true with respect to any reference, patent or otherwise, foreign or domestic. There is no basis in the statute . . . for discriminating either in favour of or against prior art references on the basis of nationality. We do know that some opinions have looked askance at foreign patent, but that it is for the reason that the patents of some countries have been notorious for containing inadequate and incomplete disclosure.

OBVIOUSNESS

The traditional test enunciated in Graham vs. John Deere Company 383 U.S. 1, 148 U.S.P.Q. 459 1966, for Section 103 nonobviousness requires the fact finder to make several determinations. The test provides that the scope and content of the prior art be determined, the differences between the prior art and the claims at issue be ascertained, and the level of ordinary skill in the pertinent art be resolved. Thus, the patentability of the claims at hand must stem from the fact that the specific combination of the claimed elements was not disclosed in the prior art and the additional allegation that the specific combination of claimed elements was nonobvious to one of ordinary skill in the art.

As further defined in Jacobson Bros. Incorporated vs. United States at 512 F.2d 1065, 185 U.S.P.Q. 168 (Ct. Cl. 1975), in reviewing the level of skill in the art, one must consider the prior art approaches employed, the types of problems encountered in

the art, the rapidity with which innovations are made, the sophistication of the technology involved, and the educational background of those actively working in the field. In considering the aforementioned factors, one may develop a picture of what the level of skill of the ordinary person skilled in the art may be.

The question of nonobviousness is a simple one to ask but difficult to answer. The person of ordinary skill in the art at the time of the invention is presumed to have before him all of the relevant prior art. The difficulty which attaches to an honest attempt to answer this question can be attributed to the strong temptation to reply on hindsight while undertaking this evaluation; combining the right references in the right way so as to achieve the result of the claims in suit. Monday morning quarterbacking is quite improper when resolving the question of nonobviousness in a court of law. What matters in Section 103 nonobviousness determination is whether a person of ordinary skill in the art having all of the teachings of the references before him is able to produce the structure defined by the claim.

Applicant again respectfully contends that none of the references either alone or in combination, would render the present invention obvious under 35 U.S.C. 103 to one skilled in the art. The "picking and choosing" and combining of references in the rejection clearly presents a case of an improper hindsight reconstruction. An improper hindsight reconstruction is one in which a rejection is construed from isolated teachings of the prior art without considering the overall context within which those teachings are presented. A rejection based on 35 U.S.C. 103 clearly must rest on a factual basis and these facts must be interpreted without hindsight reconstruction of the invention from the prior art. The case law has long upheld these principles, see e.g. In re Mercier, 185 U.S.P.Q. 774 (C.C.P.A. 1975), In re Rice, 178 U.S.P.Q. 478 (C.C.P.A. 1973), and In re Warner et al, 154 U.S.P.Q. 173 (C.C.P.A. 1967).

Likewise, the courts have long held that "obvious to try" is not the standard of 35 U.S.C. 103 and not the test of patentability, and further that it is impermissible within the framework of 35 U.S.C. 103 to "pick and choose" from parts of reference to construct a rejection. See e.g. In re Lunsford, 148 U.S.P.Q. 721 (C.C.P.A. 1966), In re Dien, 152 U.S.P.Q. 550 (C.C.P.A. 1967), In re Lindell, 155 U.S.P.Q. 521 (C.C.P.A. 1967), In re Marzocchi et al, 169 U.S.P.Q. 367 (C.C.P.A. 1971), In re Kamm et al, 172 U.S.P.Q. 298 (C.C.P.A. 1972), In re Antonie, 195 U.S.P.Q. 6 (C.C.P.A. 1977), In re Goodwin et al, 198 U.S.P.Q. 1 (C.C.P.A. 1978), and In re Yates, 211 U.S.P.Q. 1149 (C.C.P.A. 1981).

The Examiner is also reminded of a comment by Mr. Justice Hand 1935 B. G. Corporation vs. Walter Kiddle Company, 79 F.2d 20, 22 (2d Cir. 1935),

"all machines are made up of the same elements; rods, pawls, pistons, pitmans, journals, toggles, gears, cams and the like all acting their part as they always do and always must. All compositions are made of the same substances retaining their fixed chemicals properties. But the elements are capable of an infinity of permutations and the selection of that group which proves serviceable to a given need may

require a high degree of originality. It is that act of selection which is the invention."

This comment was reinforced in Reeves Instruments vs. Beckman Instruments 444 F.2d 263, 270 170 U.S.P.Q. 74 (9th Cir. 1971) and Republic Industries vs. Schlage Block Company U.S.P.Q. (7th Cir. 1979).

Applicant further submits that a correct and recent statement of the law of obviousness is presented within Windsurfing International Inc. and Fred Ostermann GMBH et al, in the Re: Sernaker reasoning of the Court of Appeal 702 F.2d 989 (Federal Circuit 1983) when it was concluded that the following related test are appropriate standards against which to make an obviousness determination:

- (a) whether a combination of the teachings of all or any of the references would have suggested (expressly or by implication) the possibility of achieving further improvement by combining such teachings along the line of the invention in suit, and
- (b) whether the claimed invention achieved more than a combination which any or all of the prior art references suggested expressly or by reasonable implication.

Referring to the Windsurfing case, it was determined that although the test (a) was satisfied, the test (b) was not satisfied because the prior art references in combination do not make an invention obvious unless something in the prior art references would suggest the advantage to be derived from combining their teachings. It was therefore concluded that the patented invention in the Windsurfing case resulted in more than a combination suggested by any of the prior art references.

Finally the Examiner is respectfully directed toward Anderson Black Rock Incorporated vs. Pavement Salvage Company Inc. 396 U.S. 57 1969, wherein it was stated that each element of the invention performed the same function together that it performed separately in the prior art. Thus the combination of elements only accomplished the performance of all of its known functions without any synergistic result and thus would be rendered unpatentable.

It is not always necessary to show the nonobviousness of the claimed invention to overcome a §103 rejection or attack. Sometimes what is alleged to be a prima facie case of obviousness is no such thing, because it is a defective or specious showing. Then there is no need at all for the applicant or patentee to go forward to show nonobviousness. All he need do is demonstrate the impropriety of the alleged prima facie obviousness showing. Some examples of such specious showings (by no means exhaustive) and the appropriate responses are set forth below. When an attempt is made to combine two references A and B, or to change a single reference, a prima facie case of obviousness has not been established if:

- (1) A and B could not or would not be physically combined in an operative fashion or to produce the desired result by a person of ordinary skill without use of the patentee's teachings. *In re Lintner*, 458 F.2d 1013, 173 USPQ 560, 562 (CCPA 1972);

In re Regel, 526 F.2d 1399, 188 USPQ 136 (CCPA 1975); *In re Jansson*, 609 F.2d 996, 203 USPQ 976 (CCPA 1979).

(2) The intended purpose or function of either A or B, or both, is destroyed by their combination. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

(3) No suggestion why or reasons or motivation for combining A and B appears explicitly or implicitly in either A or B, or both in combination. *In re Clinton*, 527 F.2d 1226, 188 USPQ 365 (CCPA 1976).

(4) A and B are from such diverse arts (i.e., either or both are nonanalogous art to the claimed invention) that a person of ordinary skill in the claimed art would not look to those arts to solve the problem treated by the claimed invention. *In re Pagliaro*, 657 F.2d 1219, 210 USPQ 888 (CCPA 1981); *In re Wood*, 599 F.2d 1032, 202 USPQ 171 (CCPA 1979); *In Re Horn*, 203 USPQ 969 (CCPA 1979).

(5) A and B, or the single reference, does not teach the source of the problem, and the recognition of the source of the problem is what is unobvious. *Eibel Process Co. v. Minnesota and Ontario Paper Co.*, 261 US 45 (1923); *In re Sponnoble*, 405 F.2d 578, 160 USPQ 237 (CCPA 1969); *In re Peehs*, 612 F.2d 1287, 204 USPQ 835 (CCPA 1980).

Once a prima facie obvious rejection is shown to be proper, and the applicant (or patentee) introduces rebuttal evidence, the examiner (or trial court) must forget that, or ignore the fact that, a prima facie case had been established. The issue of obviousness must be examined afresh. All that the prima facie showing was good for was to force the applicant or patentee to come forward with evidence of nonobviousness in technological form or the objective indicia, or both.

The systematic investigation of nonobviousness includes as relevant evidence the objective indicia of nonobviousness, the so-called "secondary considerations." Those relevant indicia include:

- (a) Long felt but unsatisfied need for the invention while the needed implementing arts and elements had long been available;
- (b) Appreciation that a problem existed and what the problem was were theretofore unseen by those skilled in the art;
- (c) Substantial attempts by those skilled in the art to fill the need of (a) or to cope with the difficulties extant because of failure to understand the problem of (b);
- (d) Commercial success of the invention causally related to the invention itself, rather than to companion factors such as advertising or attractive packaging;
- (e) Replacement in the industry of the prior art devices by the patented invention;
- (f) Prompt copying of the patentee's invention by competitors, as distinguished from their independent development thereof;
- (g) Acquiescence by the industry to the patent's validity by honoring the patent through taking licenses or not infringing the patent, or both;

- (h) Teaching away from the technical direction in which the patentee went by those skilled in the art;
- (i) Unexpectedness of the results of the invention to those skilled in the art; and
- (j) Disbelief and incredulity on the part of those skilled in the art that the patentee's approach worked.

See *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n⁵, 229 U.S.P.Q. 182, 187 n⁵ (Fed. Cir. 1986) (listing the "following tenets of patent law that must be adhered to when applying § 103: (1) the claimed invention must be considered as a whole . . . (2) the references must be considered as a whole and suggest the desirability and thus the obviousness of making the combination . . . (3) the references must be viewed without the benefit of hindsight vision afforded by the claimed invention . . . (4) 'ought to be tried' is not the standard with which obviousness is determined . . . and (5) the presumption of validity remains constant and intact throughout litigation"). For a topical outline and case tables covering the decisions of the Federal Circuit, see the separate *Guide to the Patent-Related Decisions of the Court of Appeals for the Federal Circuit* in Volume 6 of this treatise. See also Dunner, ed., "The United States Court of Appeals for the Federal Circuit - Its First Three Years," 13 AIPLA Q.J. 185 (1985); Mintz & Racine, "Anticipation and Obviousness in the Federal Circuit," 13 AIPLA Q.J. 195 (1985).

In Re: Fritch, 23 U.S.P.Q. 2d 1780 (Fed. Cir. 1992)

"Wilson and Hendrix fail to suggest any motivation for, or desirability of, the changes espoused by the Examiner and endorsed by the Board. Here, the Examiner relied upon hindsight to arrive at the determination of obviousness. It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. The court has previously stated that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention."

A synopsis of highlight §103 points and cases of the Federal Circuit follows.

Most if not all inventions are combinations of known elements; there is solely one standard of nonobviousness for all types of inventions. *Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563, 720 USPQ 97 (Fed. Cir. 1983); *Fromson v. Advanced Offset Plate, Inc.*, 720 F.2d 1565, 219 USPQ 1137 (Fed. Cir. 1983); *In re Grasselli*, 713 F.2d 731, 218 USPQ 769 (Fed. Cir. 1983); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Environmental Designs, Ltd. v. Union Oil*, 713 F.2d 693, 218 USPQ 865 (Fed. Cir. 1983). Chief Judge Markey, writing for the court in

Fromson v. Advanced Offset Plate, 755 F.2d 1549, 1556, 225 USPQ 26, 31 (Fed. Cir. 1985), took the trial court to task for its statement that the patent in suit is a "combination patent comprised exclusively of old elements." Chief Judge Markey observed that "only God works from nothing. Men must work with old elements." Judge Markey cited his article, *Why not the Statute?*", 65 JPOS 331 (1983); the old Testament could properly be relied upon as authority as well.

In ascertaining the differences between the prior art and the claims at issue (the second factual inquiry of *Graham v. John Deere*), it is essential to consider the claims at issue as "the invention as a whole," as required by §103:

- a. It is essential to consider all elements of the claimed invention; it is impermissible to compare the prior art with what the viewer interprets the "gist" of the invention to be. *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 221 USPQ 669 (Fed. Cir. 1984); *Jones v. Hardy*, 727 F.2d 1524, 1527-28, 220 USPQ 1021, 1024 (Fed. Cir. 1984) ("Reducing a claimed invention to an 'idea', and then determining patentability of the 'idea' is error."). See also, *W.L. Gore & Associates v. Garlock*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983); *ACS Hospital Systems v. Montefiore Hospital*, 732 F.2d 1572, 221 USPQ 929 (Fed. Cir. 1984); *Litton Industrial Products v. Solid State Systems Corp.*, 755 F.2d 158, 225 USPQ 34 (Fed. Cir. 1985).
- b. It is impermissible to ignore the advantages, properties, utilities, and unexpected results flowing from the claimed invention; they are part of the invention as a whole. *Fromson v. Advanced Offset Plate*, 755 F.2d 1549, 225 USPQ 26 (Fed. Cir. 1985); *In re Piasecki*, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984); *Schenck, A.G. v. Norton Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983); *In re Sernaker*, 702 F.2d 989, 217 USPQ 1 (Fed. Cir. 1983).

Criteria to be considered in determining the level of ordinary skill in the art (the third factual inquiry of *Graham v. John Deere*), as set forth in *Environmental Designs, Ltd. v. Union Oil*, 713 F.2d 693, 696, 218 USPQ 865, 868 (Fed. Cir. 1983), are:

- i. the educational level of the inventor;
- ii. type of problems encountered in the art;
- iii. prior art solutions to those problems;
- iv. rapidity with which innovations are made;
- v. sophistication of the technology; and
- vi. educational level of active workers in the field.

The prior art (item iii.) is a good indicator of the level of skill -- often it is a level inadequate to solve the problem the claimed invention successfully resolved. However, it may be that given the problem, an untutored layman (perhaps a district court judge) would immediately come up with a solution that those skilled (or

expert) in the art would reject because of technical impediments not appreciated or appreciable by a layman. *Litton Industrial Products v. Solid State Systems*, 755 F.2d 158, 225 USPQ 34 (Fed. Cir. 1985) the inquiry is not what would have been obvious "to the judge or to the common layman").

The objective indicia of nonobviousness (the "secondary considerations" of *Graham v. John Deere*) are usually the most important items of evidence available and are properly viewed as a "fourth" factual inquiry in the *Graham v. John Deere* investigation. *Simmons Fastener Corp. v. Illinois Tool Works*, 739 F.2d 1573, 1575, 222 USPQ 744, 746 (Fed. Cir. 1984). Finding obviousness through hindsight (i.e., after the fact of the invention and with the teachings of the inventor available) is impermissible and refuted by the objective indicia of nonobviousness. *In re Piasecki*, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984). *In re Sernaker*, 702 F.2d 989, 217 USPQ 1 (Fed. Cir. 1983).

Neither the PTO nor a trial court may decide the issue of obviousness without including in its evaluation the objective evidence of nonobviousness. It is impermissible for a trier of fact to say that the claimed invention is obvious and thus the evidence of nonobviousness in the form of objective indicia need not be considered. It is a requirement of due process of law that all evidence on nonobviousness, including the "secondary considerations," be weighed before reaching an ultimate conclusion on §103. *Simmons Fastener*, *supra*; *Piasecki*, *supra*; *Sernaker*, *supra*; *In re Fielder*, 471 F.2d 640, 644, 176 USPQ 300, 303 (CCPA 1973); *In re Palmer*, 451 F.2d 1100, 172 USPQ 126 (CCPA 1971).

It is well settled that obviousness under § 103 can not be established by combining the teachings of the prior art to obtain the claimed invention, absent some teachings, suggestion, or incentive supporting the combination. See *In Re: Geiger*, 2 USPQ 2d 1276 (Fed. Cir. 1987). By the same token, the Examiner can not pick and chose among the individual elements of assorted prior art references, to recreate the claimed invention. To the contrary, the Examiner has the burden to show some teachings or suggestion in the reference to support their use in the particular claimed combination. See *Smithkline Diagnostics Inc. vs. Helena Laboratories Corp.*, 8 USPQ 2d 1468 (Fed. Cir. 1988).

In fact it is well established that for a combination of references to render an invention obvious, it must be obvious that the references can be combined; *In Re Avery* 186 U.S.P.Q.161 (CCPA 1975). The references themselves and not in retrospect, must suggest what has to be done. *In Re: Skoll* 187 USPQ 481 (CCPA 1975). There must be some reason for the combination other than hindsight gleaned from their invention itself. *Interconnect Planning Corp. vs. Feil*, 774 F. 2d 1132, 1134 (Fed. Cir. 1985). See also *Panduit Corp. vs. Dennision Mfg. & Co.*, 810 F. 2d 1561, 1568 (Fed. Cir. 1988) where the court said:

"Elements of separate prior art patents cannot be combined when there is no suggestion of such combination anywhere in those patents".

Although the Examiner suggests that the structure could readily be modified to form a combination of the claims at issue, the mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification. Please See in *Re: Gordon* 733 F. 2d 900-902, 221 USPQ 1125, 1127 (Fed. Cir. 1984); *In Re: Grabiak*, 769 F. 2d 729, 731, 226 USPQ 870, 872 (Fed. Cir. 1985).

Clearly, the prior art does not suggest or provide any reason or motivation to make such a modification as purported by the Examiner. With reference to In Re: Regal, 526 F. 2d 1399, 1403 n. 6, 188 USPQ 136, 139 n. 6 (CCPA 1975).

"There must be some logical reason apparent from positive, concrete evidence of record which justifies a combination of primary and secondary references".

In Re: Geiger, 815 F. 2d 686, 688, 2 USPQ 2d 1276, 1278 (Fed. Cir. 1987) (obviousness can not be established by combining pieces of prior art absence some "teachings, suggestion, or incentive supporting the combination"); *In Re: Cho*. 813 F. 2d 378, 382, 1 USPQ 2d 1662, 1664 (Fed. Cir. 1987) ("discussing the Board's holding that the artisan would have been motivated to combine the references").

Therefore, it Applicant's view there is no evidence of motivation in the prior art, either within the references themselves, or knowledge generally available to one of ordinary skill in the art, to make the purported changes suggested by the Examiner to arrive at the claimed subject matter.

Further in re *Vaeck* , 947 F.2d 488,20 USPQ2d 1438 (Fed. Cir. 1991):

"Rejection of claimed subject matter as obvious under 35 USC 103 in view of combination of prior art references requires consideration of whether prior art would have suggested to those of ordinary skill in art that they should make claimed composition or device, or carry out claimed process, and whether prior art would also have revealed that such person would have reasonable expectation of success; both suggestion and reasonable expectation of success must be founded in prior art, not in applicant's disclosure."

It is also submitted that the following Cases update and reinforce Applicant's previously discussed excerpted case law with reference to obviousness.

Referring again to the in the *In Re Sernaker* Decision before the Court of Appeals, Federal Circuit 702 F 2d 989, 217 USPQ 1 it was stated therein;

"When one skilled in the art at the time of the invention is considering all the prior art in combination, we wholly fail to perceive what more he

would have found. The most that would have appeared to have been suggested was the use of transfer prints on rough substrates by which, no doubt, a variety of designs might have been achieved. Mating or registering are suggested nowhere in the prior art. Therefore, it does not show how to approach the results this inventor achieved. No prior art suggests expressly or by implication keeping the print off the substrate and providing a "sculptured" embroidery in a pattern to mate and register with the print."...

"The lesson of this case appears to be that prior art references in combination do not make an invention obvious unless something in the prior art references would suggest the advantage to be derived from combining their teachings. It does not appear from the opinion that the inventor actually did anything not disclosed somewhere in the prior art references, and in that regard the case was less favorable for unobviousness than the case at bar, where none of the prior art references disclosed an embroidery inserted between the print and the substrate, "registered" or mated the print with the embroidery, not the substrate, and transferred the print to the insert, not to the substrate."

It is Applicant's view that the above-mentioned excerpted sections from the In Re Sernaker decision, reinforces describe the meanings of the aforementioned broadly accepted test, as to whether a combination of the teachings of all or any of the references would have suggested (expressly or by implication) the possibility of achieving further improvement by combining such teachings along line of the invention in suit, (b) whether the claimed invention achieved more than a combination which any or all of the prior art references suggested, expressly or by reasonable implication.

Further in the Re Pleuddemann Decision of August the 3, 1990 before the Court of Appeals, Federal Circuit, 910 F 2d 823, 15 USPQ 2d 1738 the following comment is found:

"In Kuehl the court said, 475 F.2d at 664-665, 177 USPQ at 255:

The test under §103 is whether in view of the prior art the invention as a whole would have been obvious at the time it was made, and the prior art here does not include the zeolite, ZK-22. The obviousness of the process of cracking hydrocarbons with ZK-22 as a catalyst must be determined without reference to knowledge of ZK-22 and its properties. So judged, the process of the appealed claims would not have been obvious. (Emphasis ours).

In the present case likewise, §103 obviousness of claims 26 and 27 depends on the obviousness of using appellant's new compounds, which constitute the essential limitation of the claims, in light of the prior art. That being so, the board's hindsight comparison of the functioning of the new compounds with the functioning of the compounds of the prior art was legal error. It uses appellant's specification teaching as though it were prior art in order to make claims to methods of bonding/priming using his admittedly novel compounds appear to be obvious."

Referring now to the Decision of the Court of Appeals Federal Circuit In Re Bond, decided on August 3, 1990, found at 910 F 2d 831, 15 USPQ 1566, it is stated:

"We are convinced that this holding does not recognize that there are critical differences between the claimed invention and the prior art. See *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966) (the difference between the claimed invention and the prior art is one of the four factual inquiries pertinent to any obviousness inquiry under 35 U.S.C. §103). It also does not reflect the admonition of this court that "obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination." *Carella v. Starlight Archery and Pro Line Co.*, 804 F. 2d 135, 140, 231 USPQ 644, 647 (Fed. Cir. 1886); see also *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F. 2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). The Board's analysis is a classical example of a hindsight reconstruction of the claimed invention."

Referring to the Court of Appeal's, Federal Circuit Decision of April 3, 1989, In Re Laskowski, 10 USPQ 2d 1397, there is found an extensive discussion which Applicant submits should be the test for determining obviousness, in view of combining prior art references.

"Although the Commissioner suggests that Hoffman could readily be modified to form the Laskowski structure, 'the mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification.' *In re Gordon*, 733 F. 2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). See also, e.g., *Interconnect Planning Corp., v. Feil*, 774 F. 2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985); *In re Grabiak*, 769 F. 2d 729, 731, 226 USPQ 870, 872 (Fed. Cir. 1985); *In re Sernaker*, 702 F. 2d 989, 994, 217 USPQ 1, 5 (Fed. Cir. 1983).

The prior art does not suggest Laskowski's modification of the Hoffman band saw wheel, or provide any reason or motivation to make that modification. *In re Regel*, 526 F. 2d 1399, 1403 n.6, 188 USPQ 136, 139 n.6 (CCPA 1975) ('there must be some logical reason apparent from positive, concrete evidence of record which justifies a combination of primary and secondary references') (citing *In re Stemniski*, 44 F. 2d 581, 170 USPQ 343 (CCPA 1971)). We agree with the Commissioner that the suggestion to modify the Hoffman structure need not be found in Hoffman. In this case, however, the only source of the suggestion is Laskowski; there is no prior art teaching that would provide the motivation of using a loosely fitting tire, rising above the pulley flanges, to support the saw blade. See *In re Geiger*, 815 F. 2d 686, 688, 2 USPQ 2d 1276, 1278 (Fed. Cir. 1987) (obviousness can not be established by combining pieces of prior art absent some 'teaching, suggestion, or incentive supporting the combination'); *In re Cho*, 813 F. 2d 378, 382, 1 USPQ 2d 1662, 1664 (Fed. Cir. 1987) (discussing the Board's holding that 'the artisan would have been motivated' to combine the references); *In re Deminiski*, 796 F. 2d 436, 443, 230 USPQ 313, 316 (Fed. Cir. 1986)

(impropriety of hindsight reconstructions); *In re Donohue*, 766 F. 2d 531, 534, 226 USPQ 619, 622 (Fed. Cir. 1985) (referring to the 'suggestion or motivation to combine teachings' in rejections for obviousness) (citing *In re Samour*, 571 F. 2d 559, 563, 197 USPQ 1, 4-5 (CCPA 1978)); *In re Clinton* 527 F. 2d 1226, 1228, 188 USPQ 365, 367 (CCPA 1976) (holding that 'a person of ordinary skill in the art would have had sufficient motivation to combine' the separate steps); *In re Boe*, 505 F. 2d 1297, 1299, 184 USPQ 38, 40 (CCPA 1974) (discussing 'the main motivation for combining' two prior art references)."

Further in considering simplicity and improvements:

"Simplicity is no bar to invention if steps taken are not obvious to ordinary mechanic.-- *Blish, Mize & Silliman Hardware Co., v. Time Saver Tools, Inc.* (CA 10) 111 USPQ 6."

"Gross appearance is not reliable measure of invention; apparent simplicity of patented device points toward presence of invention where device for years escaped prior workers skilled in the art and made the difference between impractical suggestions and useful improvement accepted as such be those in art to which device relates.- - *Appleton Electric Co. V. Wagner Malleable Iron Co.* (DC NIII) 109 USPQ 341."

"Ease and cheapness of manufacture are not ordinarily the kind of new result upon which invention can be predicated, but they are proper evidence to consider in evaluating usefulness of patent in its field.-- *Fischer & Porter Co. v. Brooks Rotameter Co.* (DC EPa) 95 USPQ 37,"

"Narrowness and simplicity do not bar patentability; despite apparent simplicity of device, there may be invention where it appears that industry had for many years sought satisfactory device, that numerous devices had been tried and abandoned, and that patented device met with hearty response on part of users; one who produces patentable new results, the simplicity of which effects savings of time and costs, not suggested by prior references, may be entitled to patent. --*Schneider Metal Mfg. Co. v. Ernest, Inc.* (DC WPAa) 94 USPQ 109."

"Simplicity of patented structure does not negative invention.--*Baltz v. Botto* (DC WTenn) 111 USPQ 376."

"It does not necessarily negative invention or patentability that, viewed after disclosure and explanation by applicant, device seems simple and such as should have been obvious to those in field; simplicity may even be some evidence of invention.--*In re Osplack* (CCPA) 93 USPQ 306."

"Patent will not be invalidated simply because it embodies solution that seems simple and obvious with benefit of hindsight. ---*Omark Industries, Inc. v. Textron, Inc.* (CA 9, 1982) 216 USPQ 749."

"Court will not engage in hindsight; fact that invention seems simple after it is made does not determine question; many of most beneficial patents would be stricken down if this were rule. --Johns-Manville Corp. v. Guardian Industries Corp. (DC EMich, 1983) 221 USPQ 319."

"Simple: and "obvious" are not synonymous terms. --EWP Corp. v. Reliance Universal, Inc. (DC SOhio, 1983) 221 USPQ 542."

"Invention's simplicity is not to be equated with obviousness. --Ethyl Molded Products Co. v. Betts Packaging Inc. (DC EKy, 9/2/88) 0 USPQ 2d 1001."

"Invention need not be complex or superior to previous devices in order to be non-obvious. --Demaco Corp. v. F. Von Langsdorff Licensing Ltd. (CA FC, 6/21/88) 7 USPQ 2d 122."

See In Re: Fritch, 23 U.S.P.Q. 2d 1780 (Fed. Cir. 1992)

"Wilson and Hendrix fail to suggest any motivation for, or desirability of, the changes espoused by the Examiner and endorsed by the Board. Here, the Examiner relied upon hindsight to arrive at the determination of obviousness. It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. The court has previously stated that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention."

Further the Examiner is referred to the following excerpted case law recently reviewed.

In Re: Rouffet, 47 U.S.P.Q. 2d 1453 (Fed. Cir. 1998)

"As this court has stated, "virtually all [inventions] are combinations of old elements." Environmental Designs, Ltd. v. Union Oil Co., 713 F.2d 693, 698, 218 USPQ 865, 870 (Fed. Cir. 1983); see also Richdel, Inc. v. Sunspool Corp., 714 F.2d 1573, 1579-80, 219 USPQ 8, 12 (Fed. Cir. 1983) ("Most, if not all, inventions are combinations and mostly of old elements."). Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together

elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be "an illogical and inappropriate process by which to determine patentability." Sensonics, Inc. v. Aerosonic Corp., 81 F.3d 1566, 1570, 38 USPQ 2d 1551, 1554 (Fed. Cir. 1996).

To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.

This court has identified three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art. In this case, the Board relied upon none of these. Rather, just as it relied on this high level of skill in the art to overcome the differences between the claimed invention and the selected elements in the references, it relied upon the high level of skill in the art to provide the necessary motivation. The Board did not, however, explain what specific understanding or technological principle within the knowledge of one of ordinary skill in the art would have suggested the combination. Instead, the Board merely invoked the high level of skill in the field of art. If such a rote invocation could suffice to supply a motivation to combine, the more sophisticated scientific fields would rarely, if ever, experience a patentable technical advance. Instead, in complex scientific fields, the Board could routinely identify the prior art elements in an application, invoke the lofty level of skill, and rest its case for rejection. To counter this potential weakness in the obviousness construct, the suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness.

Because the Board did not explain the specific understanding or principle within the knowledge of a skilled artisan that would motivate one with no

knowledge of Rouffet's invention to make the combination, this court infers that the examiner selected these references with the assistance of hindsight. This court forbids the use of hindsight in the selection of references that comprise the case of obviousness. See *In re Gorman*, 933 F.2d 982, 986, 18 USPQ 2d 1885, 1888 (Fed. Cir. 1991). Lacking a motivation to combine references, the Board did not show a proper *prima facie* case of obviousness. This court reverses the rejection over the combination of King, Rosen and Ruddy."

Referring now to United States Patent No. 4,820,833 to Crisp et al which is a continuation of United States Patent No. 4,562,181 there is taught a process for preparing a highly pure substantially amorphous form of cefuroxime axetil which comprises preparing a highly pure solution of cefuroxime axetil and spray drying said solution to recover highly pure substantially amorphous cefuroxime axetil. In essence therefore the patent teaches as stated in column 5, line 4,

"In order to obtain cefuroxime axetil ester in highly pure form by the above techniques it is necessary to employ a starting material of suitable purity - i.e. at least as pure as the final product. Such a starting material may be obtained by any convenient method, e.g. by crystallization."

The patent therefore teaches the cefuroxime axetil and highly pure substantially amorphous form in admixtures with one or more pharmaceutical carrier and/or excipient.

In the examples, the cefuroxime axetil used as a starting material is in highly pure crystalline form which for example may be as per the process described in British Patent Specification No. 1,571,683. That material then undergoes the esterification process as described at column 6 and column 7 with respect to the preparation of crystalline cefuroxime axetil used as the starting material for the various examples.

Referring specifically to example 26, at column 11 the "R-" and the "S-" isomers of cefuroxime axetil are stirred into a flask, heated to 42 degrees and continually stirred until the solid material is totally dissolved and placed into solution and retained to be utilized in the precipitator by the addition of the prepared cefuroxime axetil solution and water into the turbulent zone thereof. The precipitated product which can only contain cefuroxime axetil is collected and de-watered. That precipitated cefuroxime axetil product is then mixed with known excipients in dry form. At no time through any of the examples or the product prepared by Example 26 were water-soluble excipients dissolved in the prepared solution with the cefuroxime axetil. In fact, the excipients are mixed with the solid active subsequent to the precipitation step and then formed into slugs which are further sieved to reduce the size of the granules prior to compressing into tablets. At no time in any of the examples, and particularly Example 26 were the excipients added to the prepared solution of the solvent and dissolved with crystalline cefuroxime axetil and subsequently precipitated therewith from the solution. Respectfully, the Examiner is reading more into the reference than what in fact is taught.

It is well understood that any materials in solution are not readily separable while in solution since they are intimately associated. Crisp et al teaches that only the cefuroxime axetil in crystalline form is placed in solution with acetone in order to prepare the amorphous form thereof.

Applicant claims the following:

A composition comprising a co-precipitate of cefuroxime axetil and a water-soluble excipient.

This composition is not taught in Crisp et al, nor is it inferred directly or indirectly from example 26 as alleged by the Examiner or from any other of the teachings of Crisp.

Referring now to the accepted case law, it is axiomatic that for prior art to anticipate it has to meet every element of the claimed invention. Exclusion of a claimed element from a prior art reference is enough to negate anticipation by that reference. In this regard, please refer to the excerpted case law above, Hybritech Inc. v. Monoclonal Antibodies, Inc., and Atlas Powder Co. v. E.I. du Pont De Nemours & Co. Therefore clearly as set out in amended Claim 1 and those depending therefrom the prior art teachings of Crisp et al does not teach Applicant's invention related to a composition comprising a co-precipitate of cefuroxime axetil and a water soluble excipient. Nowhere within Crisp et al is there a discussion of such a composition. Since all of the dependent claims 2 through 14 depend on claims 1, clearly there can be no discussion of such a composition comprising cefuroxime axetil and a water soluble excipient with the further limitations of those claims. The Crisp reference clearly does not teach such a composition.

Referring to the traditional test of Graham and John Deere, Applicant has pointed out the scope and content of the prior art and particularly Crisp et al which is silent on any compositions including a co-precipitate including both cefuroxime axetil and a water soluble excipient. Clearly this difference, set out in the amended claims, identifies over Crisp et al and therefore the only conclusion possible is that all the claims are patentable over Crisp et al, in that they are novel and non-obvious to those skilled in the art, enabling compositions of cefuroxime axetil for oral administration to be prepared which exhibit a desirable high bioavailability without requiring the use of cefuroxime axetil in highly pure amorphous form and enabling tablets for oral administration exhibiting the desired high bioavailability to be manufactured, without requiring that the tablets disintegrate immediately in

gastrointestinal fluid. Applicant has found that the water solubility and the bioavailability of the cefuroxime axetil can be enhanced by making a composition comprising a co-precipitate cefuroxime axetil and a water soluble excipient. Tablets made from the composition comprising the co-precipitate exhibit satisfactory dissolution and bioavailability even if the tablets disintegrate over a period of many minutes.

The composition is made by dissolving pure crystalline cefuroxime axetil and a water soluble excipient in a solvent and mixing until a clear solution is formed. It is then necessary to remove the solvent in order to obtain a dry composition comprising the co-precipitate. The composition comprising the co-precipitate thus formed and prepared in a dried form is then further processed into tablets by mixing the composition comprising the co-precipitate with other excipients and then processing the mixed powder including the composition comprising the co-precipitate into tablets. Alternatively, the solution of the cefuroxime axetil and the water soluble excipient may be sprayed in solution form onto the other excipients in a fluidized bed drying system.

It is known that cefuroxime axetil has a tendency to form a gel in water when left in the digestive system. This renders the cefuroxime axetil relatively difficult to ingest unless a disintegrant is provided therewith. The present invention provides a form of cefuroxime axetil, that is satisfactorily ingestable, even over periods of time approaching ten minutes or more. Clearly the tablet formed containing cefuroxime axetil in Applicant's invention includes a composition comprising the co-precipitate of cefuroxime axetil and a water soluble excipient, prepared by, for example, preparing a solution of cefuroxime axetil and the water soluble excipient prior to forming the composition comprising the co-precipitate. The resulting composition form is not highly pure amorphous cefuroxime axetil but substantially non-crystalline and co-precipitated as described above and as discussed in the attached

reported cases from the Federal Court of Canada, discussed further below, which are directly relevant to this U.S. case.

Clearly, Applicant's amended claims identify a composition which is novel and non-obvious, that is, not anticipated by the prior art cited by the Examiner nor is it obvious in view of the prior art cited by the Examiner.

Referring again to the traditional test in Graham and John Deere, Applicant has assessed the scope and content of the prior art cited by the Examiner and set out the differences between the prior art and the claims at issue. Therefore, Applicant concludes that Claim 1 as amended set out again below is therefore patentable in view of the fact that the specific combination is not disclosed in the prior art and is not obvious to one of ordinary skill in the art from the teachings of Crisp:

A composition comprising a co-precipitate of cefuroxime axetil and a water-soluble excipient.

Following the Re: Sernacker reasoning as well, Applicant's invention is not suggested directly or indirectly from a combination of the prior art since the prior art does not teach a composition comprising a co-precipitate of cefuroxime axetil and a water soluble excipient. The advantages of doing so, above-mentioned, are heretofore left unaddressed in Crisp. Applicant's invention therefore achieves more than the prior art cited by the Examiner and is clearly patentable.

There is no motivation within the Crisp reference absent Applicant's invention and the teaching thereof to arrive at Applicant's combination. In fact, Applicant submits that there is no teaching, suggestion or motivation therefore in Crisp that the

composition suggested by the Examiner (example 26) is in fact a composition allegedly comprising a co-precipitate. Crisp does not suggest the desirability of making such a composition. There is no motivation in the prior art to do so.

Clearly therefore, Applicant has amended the claims to overcome the Examiner's alleged rejections and it is requested that full reconsideration be given to the claim amendments and Applicant's arguments.

As further evidence of Applicant's submissions above-mentioned, he attaches two reported cases from the Federal Court of Canada Trial Division dated February 2, 2001, Docket No. T-806-00; Docket No. T-415-98 dated March 16, 2000, and one case before the Federal Court of Appeal, February 13, 2001, Docket No. A-184-00 before Chief Justice Noël setting out the judgment of the court specifically related to the corresponding Canadian patent to Crisp et al. The patentee Glaxo has been involved with Apotex Inc. the defendant with regard to interpretation of the claims of Canadian Patent No. 1,240,313 which is the corresponding Canadian patent to United States Patent No. 4,820,833 as verified by the attached printout. Specifically within the above-mentioned decisions, the Examiner is referred to the meaning and interpretation of the teachings and claims of the Canadian Patent No. 1,240,313 also attached. Within the reported case the comparison is made between the formulations of Apotex, the Assignee of Dr. Sherman, and the Glaxo. Within the teachings of the patent the term "*highly pure amorphous cefuroxime axetil*" had been decided by the Federal Court of Canada to mean the following as set out at page 3, item 7,

"The requirement of the '313 patent are that cefuroxime axetil be in highly pure, substantially amorphous form and that this material be mixed with other materials to form the tablet composition."

The court reviewed expert evidence from Dr. Sherman, the Applicant of the instant invention, and Dr. Shefter from the University of Colorado and Dr. Winterborn representing Glaxo's position. Mr. Justice O'Keefe had concluded in the trial case that the '313 patent claimed highly pure cefuroxime axetil which also must be in substantially amorphous form both of which must be present in a single substance. The Court, at Item 17, could not determine that the Apotex (Dr. Sherman's formulation) contained substantially amorphous cefuroxime axetil, thereafter concluding that the '313 patent was not infringed. The Court then reviewed the evidence with regard to purity with respect to the Glaxo claim requiring that the cefuroxime axetil present be "highly pure" and that there was no highly pure cefuroxime axetil present in the Apotex formulation as set out on page 7 at Item 25 of the Federal Court of Appeal Decision. The Federal Court of Appeal upheld Mr. Justice O'Keefe's construction of the claims as reviewed in Docket No. T-415-98 on page 13, at Item 35 forward wherein the claims were construed from the '313 patent and the analysis of the meaning of highly pure cefuroxime axetil that is substantially amorphous was carried out with a discussion that the only impurity present in the composition after spray drying would be small amounts of residual solvent - water and acetone and in addition impurities resulting from the formation of the cefuroxime axetil with certain listed impurities in the disclosure of the '313 patent. This is set out in page 16 of Mr. Justice O'Keefe's Decision, and with respect to the composition of Glaxo at page 17, the term "highly pure" was characterized by the Court as being composed of 100% cefuroxime axetil.

Clearly this indicates additional evidence to support that the patentee did not intend for there to be anything other than a precipitate of cefuroxime axetil and definitely in no way a co-precipitate of cefuroxime axetil and a water soluable excipient. Discussion continues on through pages 18 and 19 wherein at the bottom of page 19 termination of the construction of claim 18 is considered wherein the highly pure substantially amorphous cefuroxime axetil is mixed physically with one or more

pharmaceutical carriers or excipients. Admixing has been defined as a physical mixing together set out at Item 56 on page 20 of Mr. Justice O'Keefe's Decision at page 21. However, the Apotex formulation was described wherein crystalline cefuroxime axetil is dissolved along with sorbital in an acetone/water mixture and dried to form a co-precipitate. Apotex uses 9 parts cefuroxime axetil for one part sorbital to create it's co-precipitate. Following co-precipitation of the sorbital and the cefuroxime axetil, the composition resulting might be mixed with for example magnesium stearate and silicone dioxide and subsequent to further grinding, it might be mixed with crospovidone, and granular sodium bicarbonate with additionally magnesium stearate and silicone dioxide prior to being compressed into tablets. It is then stated at page 22 what a co-precipitate might be at paragraph 61 where Dr. Sherman, the Applicant, sets out that a co-precipitate includes a homogenous dispersal of the cefuroxime axetil and the sorbital at the molecular level. However, there is no chemical reaction and hence the mixture represents a dispersion at the molecular level and that one molecule of the co-precipitate in its smallest component part one would find by molecular weight 90% of cefuroxime axetil and 10% sorbital with possible slight variations. Dr. Sherman had submitted evidence that indicated that the impurities present in his invention of the co-precipitate were in excess of 20% including 10% sorbital and over 10% other materials. The Court therefore concluded that such a combination and a co-precipitate in the ratio of 9 to 1 of cefuroxime axetil and sorbital fell outside of the definition of "highly pure" cefuroxime axetil. At page 26, the conclusion reached at paragraph 74 is that the co-precipitate simply cannot be highly pure cefuroxime axetil and that there can be no other interpretation to the '313 patent. This was the proper construction of the patent both in at trial and before the Federal Court of Appeal of the Federal Court of Canada and respectfully as is the case with the present United States Patent Office Application of Dr. Sherman. The Examiner is encouraged to read the entire contents to reach verify this conclusion.

In view of the above submissions, Applicant respectfully submits that the amended claims in the Application are clearly allowable over the prior art Crisp et al.

Further, Applicant attaches herewith an Information Disclosure Statement pursuant to 37 C.F.R. Sub-section 1.97(b) and the required fee of \$180.00 USD.

Applicants have enclosed two cheques made payable to "The Commissioner of Patents" in the amount of \$110.00 U.S. for the one month extension of time and \$180.00 U.S. for filing the Information Disclosure Statement.

Attached hereto as Exhibit A (pages 29 to 31 of this amendment) is a marked-up version of the changes made to the claims by the present amendment. The attached pages are entitled "**EXHIBIT A – CLAIMS WITH MARKINGS TO SHOW CHANGES**".

Also attached hereto as Exhibit B (pages 32 to 34 of this amendment) are three sheets that contain a clean set of all pending claims following entry of this amendment. These sheets are entitled "**EXHIBIT B – CLEAN SET OF ALL PENDING CLAIMS FOLLOWING ENTRY OF THE PRESENT AMENDMENT**". All of the currently pending claims are consolidated in this list for the convenience of the Examiner.

Should the Examiner have any questions she is respectfully requested to contact Applicants' Agent, Neil H. Hughes at (905) 771-6414 at her convenience.

Respectfully submitted,

Neil H. Hughes, P.Eng.
Registration No. 33,636
Agent for the Applicant

NHH:mse
Enclosures

Application Serial No. 09/485,598
Group Art Unit 1615

EXHIBIT A
CLAIMS WITH MARKINGS TO SHOW CHANGES

1. (Amended) A [co-precipitate] composition comprising a co-precipitate of cefuroxime axetil and a water-soluble excipient.
2. (Amended) [A co-precipitate as in] The composition of claim 1 comprising from about 40% to about 98% by weight cefuroxime axetil and from about 2% to about 60% by weight water-soluble excipient.
3. (Amended) [A co-precipitate as in] The composition of claim 1 comprising from about 75% to about 95% by weight cefuroxime axetil and from about 5% to about 25% by weight water-soluble excipient.
4. (Amended) [A co-precipitate as in] The composition of claim 1 comprising about 90% by weight cefuroxime axetil and about 10% by weight water-soluble excipient.
5. (Amended) [A co-precipitate as in] The composition of claim 1 wherein the water-soluble excipient is selected from the group consisting of povidone, hydroxy propyl cellulose, methycellulose, lactose, mannitol and sorbitol.
6. (Amended) A process of production of [a co-precipitate] the composition of claim 1 which comprises:
 - dissolving the cefuroxime axetil and water-soluble excipient in a solvent or a mixture of solvents; and
 - evaporating the solvent or solvents.

7. (Amended) [A] The process [as in] of claim 6 wherein acetone is used as solvent.
8. (Amended) [A] The process [as in] of claim 6 wherein the solvent or solvents are evaporated by spray-drying.
9. (Amended) A pharmaceutical tablet comprising [a co-precipitate] the composition according to claim 1.
10. (Amended) [A] The pharmaceutical tablet [as in] of claim 9 further comprising a disintegrant.
11. (Amended) [A] The pharmaceutical tablet [as in] of claim 10 wherein the disintegrant is a water-insoluble cross-linked polymer.
12. (Amended) [A] The pharmaceutical tablet [as in] of claim 10 wherein the disintegrant is selected from the group consisting of croscarmellose sodium, sodium starch glycolate and crospovidone.
13. (Amended) [A] The pharmaceutical tablet [as in] of claim 10 further comprising a lubricant.
14. (Amended) [A] The pharmaceutical tablet [as in] of claim 13 wherein the lubricant is stearic acid or a metallic stearate.

Please add the following claims.

15. A composition comprising a co-precipitate of cefuroxime axetil and sorbital.
16. The composition of claim 15 comprising about 90% cefuroxime axetil and about 10% sorbital.
17. A process of production of the composition of claim 15 which comprises:
 - dissolving the cefuroxime axetil and sorbital in a solvent or a mixture of solvents; and
 - evaporating the solvent or solvents.
18. The process of claim 16 wherein acetone is used as solvent.
19. A pharmaceutical tablet comprising the composition according to claim 15.
20. The pharmaceutical tablet of claim 19 further comprising a disintegrant selected from the group consisting of croscarmellose sodium, sodium starch glycolate and crospovidone.

Application Serial No. 09/485,598
Group Art Unit 1615

EXHIBIT B
CLEAN SET OF ALL PENDING CLAIMS FOLLOWING ENTRY OF THE
PRESENT AMENDMENT

- Sub C1*
- B1*
- Sub E1*
cont
- Sub E1*
cont
1. A composition comprising a co-precipitate of cefuroxime axetil and a water-soluble excipient.
 2. The composition of claim 1 comprising from about 40% to about 98% by weight cefuroxime axetil and from about 2% to about 60% by weight water-soluble excipient.
 3. The composition of claim 1 comprising from about 75% to about 95% by weight cefuroxime axetil and from about 5% to about 25% by weight water-soluble excipient.
 4. The composition of claim 1 comprising about 90% by weight cefuroxime axetil and about 10% by weight water-soluble excipient.
 5. The composition of claim 1 wherein the water-soluble excipient is selected from the group consisting of povidone, hydroxy propyl cellulose, methycellulose, lactose, mannitol and sorbitol.
 6. A process of production of the composition of claim 1 which comprises:
 - dissolving the cefuroxime axetil and water-soluble excipient in a solvent or a mixture of solvents; and
 - evaporating the solvent or solvents.
 7. The process of claim 6 wherein acetone is used as solvent.

- B1
Cont'd
- Sub E1
Cont
8. The process of claim 6 wherein the solvent or solvents are evaporated by spray-drying.
 9. A pharmaceutical tablet comprising the composition according to claim 1.
 10. The pharmaceutical tablet of claim 9 further comprising a disintegrant.
 11. The pharmaceutical tablet of claim 10 wherein the disintegrant is a water-insoluble cross-linked polymer.
 12. The pharmaceutical tablet of claim 10 wherein the disintegrant is selected from the group consisting of croscarmellose sodium, sodium starch glycolate and crospovidone.
 13. The pharmaceutical tablet of claim 10 further comprising a lubricant.
 14. The pharmaceutical tablet of claim 13 wherein the lubricant is stearic acid or a metallic stearate.

- B2
1
- Sub C2
- Sub E1
Cont
15. A composition comprising a co-precipitate of cefuroxime axetil and sorbital.
 16. The composition of claim 15 comprising about 90% cefuroxime axetil and about 10% sorbital.
 17. A process of production of the composition of claim 15 which comprises:
 - dissolving the cefuroxime axetil and sorbital in a solvent or a mixture of solvents; and
 - evaporating the solvent or solvents.

- BG
Contd
- Sub E1
Contd
-
18. The process of claim 16 wherein acetone is used as solvent.
 19. A pharmaceutical tablet comprising the composition according to claim 15.
 20. The pharmaceutical tablet of claim 19 further comprising a disintegrant selected from the group consisting of croscarmellose sodium, sodium starch glycolate and crospovidone.